IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE FLONASE ANTITRUST LITIGATION	:	
	:	CIVIL ACTION
THIS DOCUMENT RELATES TO:	:	
	:	NO. 08-3149 (Direct)
ALL ACTIONS	:	NO. 08-3301 (Indirect)

ROXANE LABORATORIES, INC., Plaintiff,	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 09-1638
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Defendant.	:	

July _14__, 2011 **Anita B. Brody, J.**

MEMORANDUM

Flonase is a steroid nasal spray containing the active pharmaceutical ingredient fluticasone propionate ("FP") produced by Defendant SmithKline Beecham Corporation, doing business as GlaxoSmithKline PLC ("GSK").[1] Until recently, Flonase was one of the nation's top-selling drugs. Three different suits have been filed against GSK, alleging various antitrust violations stemming from GSK's conduct that supposedly delayed the entry of generic FP nasal sprays into the market. The three suits are brought by: (1) direct purchasers of Flonase in

[1] Flonase consists of both the drug, including the aqueous suspension of FP, as well as the metered, atomized spray device that delivers the drug to the active site.

American Sales Co., Inc. v. SmithKline Beecham Corp., No. 08-cv-3149 (E.D. Pa. filed July 3, 2008); (2) indirect purchasers of Flonase in IBEW-NECA Local 505 Health & Welfare Plan v. SmithKline Beecham Corp., No. 08-cv-3301 (E.D. Pa. filed July 14, 2008); and (3) Roxane Laboratories, Inc. ("Roxane"), a manufacturer of a generic FP nasal spray and competitor of GSK in Roxane Laboratories, Inc. v. SmithKline Beecham Corp., No. 09-cv-1638 (E.D. Pa. filed April 17, 2009). GSK has now moved for summary judgment under Fed. R. Civ. P. 56 in all three suits, arguing that Plaintiffs have not proven that GSK's conduct caused the delayed entry of generic FP nasal spray into the market. (No. 08-3149 (Direct) ECF No. 150; No. 08-3301 (Indirect) ECF No. 272; No. 09-1638 (Roxane) ECF No. 97).[2] For the following reasons I will **DENY** this Motion.[3]

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[2] On January 11, 2011, I denied GSK's Motion for Summary Judgment on causation grounds in the Indirect Purchaser action, because that lawsuit is brought under various state laws, and because GSK's Motion did not discuss the legal standard for causation under any of the state laws at issue. (No. 08-3301 (Indirect) ECF No. 233). On January 24, 2011, GSK filed a Motion for Leave to File a Renewed Motion for Summary Judgment on causation grounds that would include a discussion of the laws at issue in the Indirect Purchaser action. (No. 08-3301 (Indirect) ECF No. 249). On March 2, 2011, I granted GSK's Motion for Leave to File a Renewed Motion for Summary Judgment on causation grounds. (No. 08-3301 (Indirect) ECF No. 271). On March 4, 2011, GSK filed its Renewed Motion for Summary Judgment on causation grounds. (No. 08-3301 (Indirect) ECF No. 272).

[3] GSK has filed separate Motions for Summary Judgment: (1) on Noerr-Pennington grounds (No. 08-3149 (Direct) ECF No. 151; No. 08-3301 (Indirect) ECF No. 190; No 09-1638 (Roxane) ECF No. 98); and (2) in the Indirect Purchaser action (No. 08-3301 (Indirect) ECF No. 180). On June 2, 2011, I issued an Opinion dealing with GSK's Motion for Summary Judgment on Noerr-Pennington grounds. (No. 08-3149 (Direct) ECF No. 242; No. 08-3301 (Indirect) ECF No. 287; No. 09-1638 (Roxane) ECF No. 144). This Opinion only concerns GSK's Motion for Summary Judgment on causation grounds.

I. BACKGROUND[4]

In my June 2, 2011 Opinion denying GSK's Motion for Summary Judgment on Noerr-Pennington grounds (No. 08-3149 (Direct) ECF No. 151; No. 08-3301 (Indirect) ECF No. 190; No. 09-1638 (Roxane) ECF No. 98), I provided a detailed discussion of the generic drug approval process under the Hatch-Waxman Act ("Hatch-Waxman"). Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in various sections of titles 15, 21, 35, and 42 of the U.S. Code), as amended by Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, subtits. A-B, 117 Stat. 2066, 2448-64 (codified at 21 U.S.C. § 355). Specifically, I detailed the process for filing an Abbreviated New Drug Application ("ANDA")—an application to the United States Food and Drug Administration ("FDA") for permission to market generic drugs that demonstrate a certain level of bioequivalence ("BE") to an FDA-approved brand-name drug. I also set out the history behind the FDA's approval of Flonase, as well as behind GSK's alleged attempts to influence the approval of ANDAs for generic FP nasal sprays by filing citizen petitions with the FDA in May and November of 2004. In this Opinion I set out additional facts that are relevant to this Motion, which concerns Plaintiffs' allegations that GSK's conduct caused the delayed entry of Roxane's generic nasal spray into the market.

[4] For purposes of summary judgment, "the nonmoving party's evidence is to be believed, and all justifiable inferences are to be drawn in [that party's] favor." Hunt v. Cromartie, 526 U.S. 541, 552 (1999) (internal quotations omitted). Where facts are disputed, the Plaintiffs' account of the facts will be taken as true for the purposes of this Motion.

A. ANDA Approval Process

There are two sections in every ANDA: (1) a BE section that contains data meant to show that the generic drug is bioequivalent to an approved brand-name drug; and (2) a Chemistry and Manufacturing Controls ("CMC") section that describes the active and inactive pharmaceutical ingredients used in the drug, as well as the controls in place to ensure that the ingredients meet certain quality and consistency standards. When the FDA receives an ANDA, it reviews the BE section of the ANDA in a process known as "BE review" to determine whether the ANDA demonstrates BE compliance. The FDA separately reviews the CMC section of the ANDA in a process known as "chemistry review." The chemistry review assesses whether the quality controls in the CMC section are sufficient to ensure product quality and manufacturing consistency. The chemistry review also determines whether the proposed source of the active pharmaceutical ingredient ("API") complies with FDA requirements.

If the FDA identifies a problem with an ANDA, it contacts the applicant through a "deficiency notice." If the problem is minor, the FDA may simply contact the applicant's regulatory liaison to resolve the issue via telephone. Such problems are expected to be resolved within sixty days after they are identified. If the problem is more substantial, however, it is classified as a "major amendment." For such problems, the FDA issues a deficiency notice identifying the issue that requires an amendment. The FDA expects to resolve these deficiencies within six months after they are identified.

B. United States Pharmacopeia and the Monograph for FP

United States Pharmacopeia ("USP") is a non-governmental organization that issues a compendium of drug standards for use in the pharmaceutical industry. Although USP is not a

governmental body, federal law specifically incorporates its standards. See 21 U.S.C. §§ 351(a)-(b), 352(e)-(g), 355(u)(3)(A). The FDA regularly consults USP standards as a reference point when issuing its own pharmaceutical standards.

USP issues "monographs" for specific drug compounds; these monographs list tests, procedures, and acceptance criteria related to the quality, purity, strength, and consistency standards for the pharmaceutical ingredients in an approved drug. When a USP monograph is modified or published, the FDA generally permits any drug manufacturers affected by the new monograph to exhaust existing supplies of their non-compliant drugs, but requires future batches to comply with the USP monograph.

As early as 2001, GSK began to consider working with USP to publish a monograph for FP. Although it is unclear exactly when it began to actually work towards a monograph, GSK eventually submitted a proposed monograph to USP. GSK's proposed monograph imposed higher standards than those outlined in the FDA's Draft Guidances. In March 2005, after GSK filed its two citizen petitions, USP published its monograph for FP, which incorporated GSK's higher standards. On April 1, 2005, USP finalized the monograph.

C. Roxane Works With the FDA to Remedy Deficiencies in its ANDA

In 2003, the FDA began its BE and chemistry reviews of Roxane's ANDA. Between 2003 and 2006, the FDA identified a number of deficiencies in Roxane's ANDA that Roxane was required to address before the FDA would approve Roxane's ANDA. During this period, in May and November of 2004, GSK filed citizen petitions with the FDA requesting that the FDA change its positions on various standards and specifications governing ANDAs for a suspension-based FP nasal spray like Roxane's. The arguments raised in these petitions are discussed in

greater detail in my Noerr-Pennington Opinion. For purposes of this Motion, what is important is simply that: (1) GSK filed citizen petitions in May and November of 2004; (2) the May and November petitions requested that the FDA refrain from approving any ANDA before resolving the petitions; and (3) on February 22, 2006, the FDA denied GSK's requests in full.

1. Early Deficiencies and the FDA's June 2004 Suggestion that Approval Was Imminent

The FDA began its chemistry review in March 2003, and began its BE review in November 2003.

(a) Early BE Review

In December 2003, soon after the FDA began its BE review, the FDA concluded that Roxane demonstrated BE compliance using the population bioequivalence method.[5] In addition, the FDA recognized that Roxane's data did not show BE compliance using the geometric mean ratio method, but nevertheless concluded that the population bioequivalence method was sufficient to show BE compliance.

In its December 2, 2003 report, the FDA found no deficiencies in Roxane's in vitro BE data, and merely requested additional information on Roxane's in vivo clinical testing procedures. On December 19, 2003, Roxane provided the requested information. Finally, in

[5] The population bioequivalence method considers the average difference in therapeutic response to two compounds as well as the variability of the responses to each compound (variability measures the rate of deviation in the response to a single compound over a series of tests). The geometric mean ratio method, on the other hand, does not consider intra-product variability; that is, "two products could deliver the same dose on the average, but if one product delivered the intended dose consistently and the other product inconsistently" the products would be BE compliant using the population bioequivalence method, but would not be BE compliant using the geometric mean ratio method. Pls. Ex. 108 at 12, 14 (Rodda Decl.).

February 2004 an internal FDA review of Roxane's bioequivalence data found that "[f]rom the bioequivalence viewpoint, [Roxane] has met the requirements of formulation sameness, device comparability, in vitro and in vivo performance testing." Def. Ex. 46 at 8 (Report, FDA Division of Bioequivalence, Feb. 11, 2004).

(b) Early Chemistry Review

Between March 2003 and May 2004, Roxane worked with the FDA to remedy a number of deficiencies relating to Roxane's API. On May 19, 2004, Roxane held a teleconference with the FDA to discuss what Roxane believed would be the final deficiency in its CMC section. The FDA agreed that the remaining deficiency was minor and indicated that its chemistry review was nearing completion.

(c) Preparations to Enter Market After FDA Suggests that ANDA Approval Is Imminent

In May 2004, after the FDA indicated that its chemistry review was almost complete, Roxane anticipated an imminent product launch. Roxane began to manufacture units for sale, preparing to produce approximately four million units of FP nasal spray.

In June 2004, the FDA informed Roxane that its chemistry review was complete and that there were "no additional questions at this time." Def. Ex. 48 (E-mail from Elizabeth Ernst, June 9, 2004). The FDA also stated that its BE review was nearly complete—in vitro review was complete, but the FDA still needed to complete a secondary review of Roxane's in vivo clinical studies. The FDA suggested that "there is an outside chance we could have approval by late 7/04 but more then [sic] likely it will occur by 8/04 . . . ." Id. In view of this estimate, Roxane

continued preparations to come to market in July or August 2004 with four million units of its generic FP nasal spray.

2. Deficiencies Issued After GSK's Citizen Petitions

(a) BE Review

Despite stating in June 2004 that ANDA approval was imminent, in October 2004 the FDA reversed its position regarding the appropriate statistical method for determining BE compliance. On October 18, 2004, the FDA issued a deficiency notice raising publicly for the first time the fact that Roxane's data did not demonstrate BE compliance using the geometric mean ratio method (the "BE Deficiency"). Def. Ex. 50 (BE Deficiency). The FDA informed Roxane that despite showing BE compliance using the population bioequivalence methodology (which was endorsed in the 1999 Draft Guidance), Roxane needed to demonstrate BE compliance using the geometric mean ratio method. In order to do so, Roxane had to re-run its clinical trials to generate additional data, delaying the approval of Roxane's ANDA.

On June 6, 2005, Roxane submitted additional data to the FDA. This data still did not demonstrate BE compliance using the geometric mean ratio method. Nevertheless, the FDA concluded on August 9, 2005 that the population bioequivalence method was sufficient to show BE compliance just as it had concluded in December 2003. At this point, over one year after the FDA had estimated it would complete its review of Roxane's ANDA, the FDA's BE review was complete.

(b) Chemistry Review

Although the FDA stated in June 2004 that its chemistry review was complete, on November 9, 2004 the FDA sent Roxane a deficiency notice indicating that the FDA was

revisiting Roxane's chemistry review (the "Impurity Deficiency"). Def. Ex. 37 (Impurity Deficiency). The Impurity Deficiency requested that Roxane tighten its API impurity specification from "no more than 0.2-0.3%" to "no more than 0.15%," or alternatively that Roxane conduct additional safety tests.

On February 1, 2005, Roxane submitted a response to the FDA stating that it had tightened its API impurity specifications to "no more than 0.15%," as requested, for all but two molecules. Roxane also attached the results from clinical tests relating to the new specifications.

On March 24, 2005, before the FDA reviewed Roxane's tightened API impurity specifications, the FDA issued a deficiency notice concerning the USP monograph for FP that would be finalized on April 1, 2005 (the "USP Deficiency"). Def. Ex. 40 (USP Deficiency). Although Roxane's API had been deemed acceptable, it "became unsatisfactory after the issuance of USP Monograph for Fluticasone Propionate." Def. Ex. 41 at 11 (Report, FDA Division of Chemistry, Aug. 2005). From May 2005 to August 2005, the FDA negotiated with Roxane, emphasizing its concern that Roxane's API did not meet the purity standards in the USP monograph. Finally on August 4, 2005, Roxane informed the FDA that it would address the FDA's concerns and utilize a different type of API that complied with the new USP monograph.

On August 9, 2005, the FDA concluded that Roxane had addressed both the Impurity and USP Deficiencies and re-approved the chemistry section of Roxane's ANDA. Def. Ex. 41.

3. Roxane Struggles to Acquire USP-Compliant FP

While Roxane negotiated with the FDA from March 2005 until August 2005 over the type of API to be used in its nasal spray, the third-party manufacturer of Roxane's FP notified Roxane on May 13, 2005 that it had 35 kilograms of USP-compliant FP that could be used to

manufacture a large quantity of FP nasal spray. Because negotiations regarding the need to use USP-compliant FP were ongoing, Roxane declined to acquire this FP.

Roxane waited until August 2005, after the FDA had completed its chemistry review and after Roxane had committed to use USP-compliant FP, to place an order for approximately 30 kilograms of USP-compliant FP. Taking into account the time to ship the FP and the typical rate of production, Plaintiffs estimate that Roxane had the ability to manufacture approximately one million units of USP-compliant FP nasal spray within four weeks. Roxane did not actually start manufacturing, however, until October 2005. Roxane produced a sufficient quantity for a commercial launch by late November 2005.

Finally, on February 22, 2006, the same day that the FDA rejected GSK's citizen petitions, the FDA formally approved Roxane's ANDA.

II. LEGAL STANDARD

Summary judgment will be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). There is a "genuine" issue of material fact if the evidence would permit a reasonable jury to find for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The "mere existence of a scintilla of evidence" is insufficient. Id. at 252.

The moving party must make an initial showing that there is no genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The non-movant must then "make a showing sufficient to establish the existence of [every] element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322; see also Fed. R. Civ. P. 56(c)(1). The non-moving party must "do more than simply show that there is some

metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). In determining whether the non-moving party has established each element of its case, the court must draw all reasonable inferences in the non-moving party's favor. Id. at 587.

III. DISCUSSION

GSK moves for summary judgment in all three pending suits, that is in the Direct Purchaser action, the Indirect Purchaser action, and in Roxane, arguing that Plaintiffs cannot show that GSK's conduct was the actual cause of Roxane's delayed entry into the market.[6] GSK argues that even absent GSK's conduct, Roxane would still have had to resolve outstanding chemistry and bioequivalence deficiencies with the FDA, and would still have had to acquire USP-compliant API, and thus would not have entered the market until August 2005 at the earliest.

A. The Causation Requirement

Plaintiffs in the Direct Purchaser and Roxane actions bring suit under federal antitrust laws, seeking to recover damages under Section 4 of the Clayton Antitrust Act, 15 U.S.C. § 15. Indirect Purchasers raise the following claims in their Corrected Third Amended Class Action Complaint (No. 08-3301 (Indirect) ECF No. 102): (1) unlawful monopolization under the laws of Arizona, Iowa, Wisconsin, and North Carolina; (2) violation of the Unfair and Deceptive Trade

[6] In the Roxane case, the alleged injury is the delayed entry of Roxane's generic FP spray into the market. In the Direct Purchaser and Indirect purchaser cases, the alleged injury is the overcharges suffered by the Plaintiffs, who were forced to purchase more expensive brand-name Flonase because Roxane's cheaper generic spray had not entered the market.

Practices ("UDTP") laws in Arizona, Florida, Massachusetts, and North Carolina; and (3) unjust enrichment in Arizona, Iowa, Massachusetts, and Wisconsin.

In order to recover damages under Section 4 of the Clayton Antitrust Act, 15 U.S.C. § 15, a plaintiff must show: "(1) a violation of the antitrust laws . . . , (2) individual injury resulting from that violation, and (3) measurable damages." In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3d Cir. 2008). The second element is known as the "causation" requirement. See, e.g., Callahan v. A.E.V., Inc., 182 F.3d 237, 250 (3d Cir. 1999) ("[A] plaintiff must prove a causal connection between [the antitrust violation] and actual damage suffered." (quoting Stelwagon Mfg. Co. v. Tarmac Roofing Sys., Inc., 63 F.3d 1267, 1273 (3d Cir. 1995))); Rossi v. Standard Roofing, Inc., 156 F.3d 452, 483 (3d Cir. 1998) ("To recover damages, an antitrust plaintiff must prove causation . . . .").[7]

The causation requirement requires a plaintiff to show that the defendant's antitrust violation was a "material cause" of the plaintiff's injury. Am. Bearing Co. v. Litton Indus., Inc., 729 F.2d 943, 952 (3d Cir. 1984) (citing Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 114 n.9 (1969)). An antitrust violation is a "material cause" of an injury if it is a proximate cause of that injury. See 2660 Woodley Rd. Joint Venture v. ITT Sheraton Corp., 369

[7] Some courts consider causation to be part of the "antitrust injury" requirement, which generally requires both that an injury be "of the type the antitrust laws were intended to prevent" and that the injury "flow[] from that which makes [the] defendants' acts unlawful." W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 101 (3d Cir. 2010) (quoting Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977); see also Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990) ("[An] injury, although causally related to an antitrust violation, nevertheless will not qualify as an 'antitrust injury' unless it is attributable to an anti-competitive aspect of the practice under scrutiny . . . ."). Because this Motion only addresses causation, it is irrelevant whether causation is part of the antitrust injury requirement or is a separate requirement.

F.3d 732, 740 (3d Cir. 2004) ("[T]he [Supreme] Court read the antitrust statutes in light of their common law background and read a proximate cause element into § 4 [Clayton Act] actions." (internal quotation marks omitted)).[8] The doctrine of proximate cause in the antitrust context considers whether the alleged injury is too remote to be fairly attributed to the asserted antitrust violation. See Allegheny Gen. Hosp. v. Phillip Morris, Inc., 228 F.3d 429, 439 (3d Cir. 2000) (rejecting an antitrust claim where the "injuries [were] too remotely connected in the causal chain from wrongdoing"). "[T]he presence of the requisite causation is normally a question of fact for a jury . . . ." Rivas v. City of Passaic, 365 F.3d 181, 193 (3d Cir. 2004). See also Callahan v. A.E.V., Inc., 182 F.3d 237, 257 (3d Cir. 1999) (declining to rule on causation in an antitrust case as a matter of law, holding instead that causation was an issue[ ] of fact best left to the jury").

An antitrust violation can be the proximate cause of a plaintiff's injury even if there are additional independent causes of the injury. Zenith Radio, 395 U.S. at 114 n.9. "On occasion, however, an independent cause fully accounts for the plaintiff's alleged injury and breaks the causal connection between the alleged antitrust violation and the plaintiff's injury." In re Wellbutrin SR Antitrust Litig., 281 F. Supp. 2d 751, 756 (E.D. Pa. 2003) (citations omitted); see also Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1060 (8th Cir. 2000) (holding

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[8] Plaintiffs cite to Argus Inc. v. Eastman Kodak Co., 801 F.2d 38, 41 (2d Cir. 1986), for the proposition that a plaintiff need only show "but-for" cause—i.e., that the plaintiff's injury would not have occurred but for the defendant's antitrust violation. The Third Circuit has emphatically rejected "but-for" causation in the antitrust context, however, as being overly broad. See McCullough v. Zimmer, Inc., 382 F. App'x 225, 229 n.4 (3d Cir. 2010) (holding that "causation in this but-for sense . . . is [not] sufficient to enable any complaint to withstand a motion to dismiss" where the injuries were not "inextricably intertwined" with the antitrust violation); Gregory Mktg. Corp. v. Wakefern Food Corp., 787 F.2d 92, 95 (3d Cir. 1986) (same). In this Circuit, but-for causation "is necessary for a finding of proximate cause, [but] it is not sufficient by itself." Allegheny Gen. Hosp. v. Phillip Morris, Inc., 228 F.3d 429, 439 (3d Cir. 2000).

plaintiffs failed to show causation because they "failed to account for 'numerous intervening economic and market factors which . . . may have been the actual cause[s] of the plaintiffs' injuries'" (quoting Greater Rockford Energy & Tech. Corp. v. Shell Oil Co., 998 F.2d 391, 402 (7th Cir. 1993))). "When a defendant relies upon the existence of an independent cause, however, such cause must be examined closely to make sure that it is the independent cause, rather than the illegal antitrust action, that gives rise to the plaintiff's injury." In re Wellbutrin SR, 281 F. Supp. 2d at 756 (internal quotation marks omitted). In other words, even if intervening conduct contributed to a plaintiff's injury, defendant's conduct still might be a proximate cause of the injury. "Proximate cause and intervening cause are usually issues for the jury to decide." Wortley v. Camplin, 333 F.3d 284, 295 (1st Cir. 2003).

Even if an antitrust violation is not the material cause of an injury and the only material cause is some intervening conduct, courts have consistently found the causation requirement satisfied and the chain of causation intact where that intervening conduct was the foreseeable consequence of the original antitrust violation. Spear Pharm., Inc. v. William Blair & Co., 610 F. Supp. 2d 278, 280-81 (D. Del. 2009) (holding that the FDA's delay in approving a generic manufacturer's ANDA did not break the chain of causation originating from the defendant's citizen petition); Dr. Reddy's Labs., Ltd. v. aaiPharma Inc., No. 01-cv-10102, 2002 WL 31059289, at *10-11 (S.D.N.Y. Sept. 13, 2002) (same). Whether conduct constitutes intervening conduct that breaks the chain of causation and whether intervening conduct is a foreseeable consequence of a defendant's actions are questions of fact to be submitted to the jury. See Marshall v. Mintz, 386 F.2d 415, 416 (5th Cir. 1967) (holding that issues of "proximate cause,

concurrent causes, foreseeability and continuing sequence, [and] independent intervening causes" were properly submitted to the jury).

If Plaintiffs' evidence is sufficient to satisfy the causation requirement under the Clayton Act, it is also sufficient to satisfy the causation requirement for Indirect Purchasers' Unlawful Monopolization and Unfair and Deceptive Trade Practices ("UTDP") claims.[9] Similarly, Unjust Enrichment claims in each of the states at issue have been interpreted to require, in antitrust cases, something comparable to causation in order to show that it would be unjust or inequitable for the defendant to retain any excess profits. Johnson v. Ariz. Hosp. & Healthcare Ass'n, No. 07-cv-1292, 2009 WL 5031334, at *7 n.4 (D. Ariz. July 14, 2009) (holding that to show unjust enrichment, "Plaintiffs will need to prove basically the same set of facts required for antitrust

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[9] All of the Unlawful Monopolization statutes at issue are interpreted under federal law, and include a causation requirement indistinguishable from that under the Clayton Act. See Ariz. Rev. Stat. § 44-1412; Bunker's Glass Co. v. Pilkington, PLC, 75 P.3d 99, 106 (Ariz. 2003); Iowa Code § 553.2; Fed. Land Bank of Omaha v. Tiffany, 529 N.W.2d 294, 296 (Iowa 1995); Crouch v. Crompton Corp., Nos. 02-4375, 03-2514, 2004 WL 2414027, at *9 (N.C. Super. Ct. Oct. 28, 2004); Adams v. Aventis, S.A., No. 01-cv-2119, 2003 WL 22015384, at *3-4 (N.C. Super. Ct. Aug. 26, 2003); Strang v. Visa USA, Inc., No. 03-cv-11323, 2005 WL 1403769, at *4 (Wis. Cir. Ct. Feb. 8, 2005). I previously held that Indirect Purchasers' North Carolina UDTP claim derives from the same statute, and thus has the same requirements as their North Carolina Unlawful Monopolization claim. (No. 08-3301 (Indirect) ECF No. 82).

The other three UDTP statutes at issue are interpreted in accordance with Section 5 of the Federal Trade Commission ("FTC") Act, 15 U.S.C. § 45. See Ariz. Rev. Stat. Ann. § 44-1522(C); Fla. Stat. § 501.204(2); Mass. Gen. Laws ch. 93A, § 2(b). The causation requirement under the FTC Act is broader than that under the Clayton Act and does not require a showing "that the defendants' conduct proximately caused harm to consumers." FTC v. Hope Now Modifications, LLC, No. 09-cv-1204, 2010 WL 1463008, at *1 (D.N.J. Apr. 12, 2010). Rather, the causation requirement under Section 5 is satisfied if the defendants' conduct was simply likely to cause harm. FTC v. Neovi, Inc., 604 F.3d 1150, 1155-57 (9th Cir. 2010) (holding that the causation requirement was satisfied where the defendant continued to engage in questionable conduct despite the clear possibility that it would cause harm). Thus if Plaintiffs can show proximate causation under the Clayton Act standard, they necessarily show causation under the broader FTC Act standard.

impact"); In re G-Fees Antitrust Litig., 584 F. Supp. 2d 26, 29-30 (D.D.C. 2008) (holding that a properly pled antitrust claim would necessarily be sufficient to show unjust enrichment under Wisconsin law); cf. Southard v. Visa U.S.A. Inc., 734 N.W.2d 192, 195 (Iowa 2007) (comparing an antitrust claim to an unjust enrichment claim under Iowa law); Eon Labs., Inc. v. SmithKline Beecham Corp., 298 F. Supp. 2d 175, 183 (D. Mass. 2003) (comparing an antitrust claim to an unjust enrichment claim under Massachusetts law). As a result, if I deny GSK's Motion as to Plaintiffs' federal law claims, I must also deny the Motion as to Indirect Purchasers' state law claims.

B. Causation As Applied to GSK's Conduct

GSK argues that its conduct did not cause Roxane's delayed entry into the market. Instead, GSK argues, the FDA's deficiency notices and Roxane's search for USP-compliant API were independent intervening causes of Roxane's delayed entry.[10] According to GSK, this intervening conduct severs the causal chain that begins with GSK's alleged antitrust violations, and GSK's conduct thus did not proximately cause Roxane's delayed entry.

[10] GSK also notes that two other generic firms filed citizen petitions with the FDA raising concerns with the approval process for ANDAs for FP nasal sprays, and that the FDA dealt with GSK's petitions together with these generic petitions. GSK argues that Plaintiffs have not shown that it was GSK's petitions, as opposed the two generic petitions, that caused Roxane's delayed approval. But they have. James Morrison, Plaintiffs' expert on the FDA's ANDA approval process, testified that the generic petitions raised minor concerns that would have been dealt with expeditiously and that would not have caused the two-year delay that resulted from GSK's petitions. Morrison Rep. ¶ 24. Morrison's testimony is supported by reference to the FDA's collective response to the pending petitions; the FDA spent only a few paragraphs discussing the issues raised in the generic petitions. This evidence is sufficient to create a genuine issue of fact as to whether the generic petitions, as opposed to GSK's petitions, were the cause of Roxane's delayed entry into the market.

Intervening conduct does not sever the chain of causation, however, where that conduct was in turn proximately caused by the defendant's antitrust violation. Intervening conduct also does not sever the chain of causation where that conduct was a foreseeable consequence of the original antitrust violation. Whether intervening conduct was proximately caused by or was the foreseeable consequence of a defendant's actions is a question of fact that can "be addressed as a matter of law only where the outcome is clear or when highly extraordinary events or conduct take[] place." Thabault v. Chait, 541 F.3d 512, 524 (3d Cir. 2008).

Plaintiffs respond to GSK's Motion with evidence tending to show that the intervening conduct cited by GSK was proximately caused by, or was the foreseeable consequences of, GSK's antitrust violations. As detailed below, Plaintiffs' evidence is sufficient to raise genuine issues of material fact as to whether the intervening conduct cited by GSK was indeed proximately caused by, or was the foreseeable consequences of, GSK's alleged antitrust violations. By raising these factual disputes, Plaintiffs have provided sufficient evidence to survive summary judgment on GSK's Motion; the question whether each instance of intervening conduct cited by GSK severs the causal chain between GSK's conduct and Plaintiffs' injuries remains a question of fact.[11]

[11] GSK separately argues that, if the court concludes that GSK did not cause Plaintiffs' injuries prior to August 2005, certain Plaintiffs lack standing to bring suit because they only made purchases between August 2004 and August 2005. Because genuine issues of fact remain as to whether GSK's conduct delayed Roxane's entry into the market beginning as early as August 2004, and because GSK does not dispute that Plaintiffs have provided evidence of purchases made between August 2004 and Roxane's entry into the market, I do not need to decide this issue.

1. The BE Deficiency

GSK argues that the BE Deficiency, which required Roxane to demonstrate BE compliance using the geometric mean ratio method, was an intervening cause of Roxane's delayed entry into the market that severs the causal chain beginning with GSK's conduct. Plaintiffs argue that the BE Deficiency was either proximately caused by, or was a foreseeable consequence of, the threat of litigation communicated by GSK's citizen petitions.

Plaintiffs' evidence suggests that by June 2004, the FDA had virtually completed the BE review of Roxane's ANDA; but for GSK's May petition, Roxane's ANDA would have been approved by August 2004. Morrison Rep. ¶ 68; Def. Ex. 46 at 3 (Report, FDA Division of Bioequivalence, Feb. 11, 2004) (concluding that "[t]he in vitro and in vivo studies have been found acceptable. The application is now acceptable with no deficiencies"); Def. Ex. 48 at 1-2 (noting that the FDA stated that BE review was almost complete, except for a secondary review of Roxane's in vivo clinical studies, and that the FDA expected to be complete by late July or August 2004).

Plaintiffs' FDA expert James Morrison states that GSK's May petition was viewed by the FDA as a "shot across the bow" signaling GSK's intent to bring suit against the FDA. Morrison Rep. ¶ 65. Once the FDA is threatened with litigation, the FDA's legal counsel "become[s] involved in the [ANDA] approval process, where they have a strong influence on the reviews of pending ANDAs." Id. ¶ 66. The FDA's counsel slows down the ANDA approval process in an attempt to "eliminate potential issues in an attempt to narrow the scope of the possible lawsuit." Id. ¶¶ 66, 68. Plaintiffs' evidence thus suggests that the FDA reversed its position regarding the geometric mean ratio in an attempt to narrow the scope of an impending GSK lawsuit; in other

words, GSK's citizen petitions may have caused the FDA to issue the BE Deficiency out of fear of future litigation.

Plaintiffs' evidence also suggests that the BE Deficiency was a foreseeable consequence of the May petition. Given that the FDA's established practice when it is threatened with litigation is to take extra precautions by requiring ANDA applicants to meet additional requirements as a condition for approval, it may have been reasonably foreseeable to a party filing a citizen petition that the FDA would view the petition as a threat of future litigation that the approval of pending ANDAs would be delayed.

An alleged intervening cause will not sever the chain of causation if it is the proximate cause of, or is a foreseeable consequence of a defendant's antitrust violation. Plaintiffs' evidence raises genuine issues of fact on both fronts: both as to whether the FDA's decision to require Roxane to demonstrate BE compliance by the geometric mean ratio method was proximately caused by the threat of litigation communicated to the FDA by way of GSK's citizen petitions, and as to whether the FDA's decision was a a foreseeable consequence of the same intervening conduct. Because a reasonable jury could conclude, based on Plaintiffs' evidence, that the BE Deficiency does not sever the chain of causation, I cannot decide this issue as a matter of law; Plaintiffs evidence is sufficient to allow the issue to remain a question of fact.

2. The Impurity Deficiency

GSK argues that the Impurity Deficiency was an intervening cause of Roxane's delay because Roxane's chemistry review was not completed until the Impurity Deficiency was resolved. As with the BE Deficiency, Plaintiffs respond that the Impurity Deficiency was

proximately caused by, or was the foreseeable consequence of, the threat of litigation imparted to the FDA by GSK's citizen petitions.

Plaintiffs' evidence shows that in June 2004 the FDA had completed its chemistry review of Roxane's ANDA. Def. Ex. 48 at 1 ("CMC review completed - no additional questions at this time[.]"); Def. Ex. 31 at 3 (Report, FDA Division of Chemistry) ("Recommendation and Conclusion on Approvability[:] Chemistry Completed."); Morrison Rebuttal Rep. ¶ 37 ("The chemistry review had been completed in June 2004.").[12] Plaintiffs evidence further suggests that despite the FDA's initial sign-off in June 2004, legal counsel issued the Impurity Deficiency to narrow the scope of future litigation after the "show across the bow" signaled by GSK's citizen petitions, just as counsel had done with the BE Deficiency. Morrison Rebuttal Rep. ¶ 48 ("GSK's May 2004 Petition and the threat of a lawsuit by GSK, caused the FDA to 'revisit' the chemistry issues (as it had revisited the bioequivalence review)."). Plaintiffs provide evidence that absent the threat of litigation, the FDA would have addressed these impurity issues in post-marketing supplements (thus allowing Roxane to enter the market) and would not have required them to be resolved as a condition of ANDA approval. Id. ¶ 37 ("In the absence of GSK's May 2004 Petition, and the threat of a lawsuit by GSK . . . the FDA would not have required Roxane to [address its API impurity issues] as a condition of approval.").

Plaintiffs' evidence shows that, as with the BE Deficiency, the Impurity Deficiency may have been proximately caused by the threat of litigation signaled by GSK's citizen petitions.

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[12] On January 14, 2011, GSK moved to strike the rebuttal report of James Morrison as procedurally improper. On July 13, 2011, I denied GSK's Motion. (No. 08-3149 (Direct) ECF No. 246; No. 08-3301 (Indirect) ECF No. 291; No. 09-1638 (Roxane) ECF No. 147).

Additionally, for the same reasons that Plaintiffs' evidence showed the BE Deficiency may have been a foreseeable consequence of the GSK's citizen petitions, the Impurity Deficiency also may have been a foreseeable consequence of the petitions.

Again, an alleged intervening cause will not sever the causal chain if it is the proximate cause of, or is a foreseeable consequence of a defendant's antitrust violation. As with the BE Deficiency, Plaintiffs have raised genuine issues of fact both as to whether the Impurity Deficiency was proximately caused by the threat of litigation communicated to the FDA by way of GSK's citizen petitions, and as to whether the Impurity Deficiency was a foreseeable consequence of the same intervening conduct. Because a reasonable jury could conclude, based on Plaintiffs' evidence, that the Impurity Deficiency does not sever the causal chain, I cannot decide this issue as a matter of law; Plaintiffs evidence is sufficient to allow the issue to remain a question of fact.

3. The USP Deficiency

GSK argues that the FDA's decision to require USP compliance as a condition of ANDA approval is an intervening cause of Roxane's delayed entry between March 2005, when Roxane was notified of the deficiency, and November 2005, when Roxane had produced enough USP-compliant units of its nasal spray for a commercial launch. Plaintiffs respond that GSK's interactions with USP, a separate antitrust violation alleged by the Plaintiffs, proximately caused the USP Deficiency.

Plaintiffs' evidence, when taken in the light most favorable to Plaintiffs, suggests that GSK influenced USP to include heightened chemistry standards in its monograph, that USP adopted GSK's suggested heightened standards, that the FDA adopted USP's monograph,

including its heightened standards, and finally that the FDA issued the USP Deficiency which required Roxane to comply with the USP monograph as a condition of ANDA approval. Gaby Dep. 210:7-215:5, Jan. 6, 2010; Vana Dep. 87:10-15, Dec. 3, 2009; Davis Dep. 32:19-34:16, Jan. 15, 2010; Morrison Rebuttal Rep. ¶¶ 46-48; Def. Ex. 41 at 11. Plaintiffs evidence thus shows that the USP Deficiency may have been proximately caused by GSK's communications with USP relating to the USP monograph.

This causal chain involves several intervening decisions by third parties, and a jury may ultimately conclude that either USP's decision to issue the monograph, or the FDA's decision to require compliance with the monograph, was not proximately caused by GSK's conduct. Whether conduct constitutes a proximate or intervening cause, however, is a question of fact for the jury. Wortley, 333 F.3d at 295. A reasonable jury could conclude based on Plaintiffs' evidence that GSK's communications with USP proximately caused the USP Deficiency, which in turn delayed Roxane's entry into the market between March 2005 and November 2005. At this stage of the litigation, Plaintiffs' evidence is sufficient to allow this issue to remain a question of fact.[13]

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[13] Some courts have held that in certain circumstances, an independent decision by a government entity may sever the chain of causation. See, e.g., Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 818 (D.C. Cir. 2001) ("If anticompetitive harm is caused by the decision of a court, even though granted at the request of a private party, no private restraint of trade occurs because the intervening government action breaks the causal chain."); City of Moundridge v. Exxon Mobil Corp., 471 F. Supp. 2d 20, 37 (D.D.C. 2007) ("When government action is the source of an alleged antitrust violation, the private party is immune because 'the intervening government action breaks the causal chain.'" (quoting Andrx, 256 F.3d at 817)). GSK may be entitled to some relief under Andrx for the period during which Roxane lacked the ability to manufacture a nasal spray with USP-compliant FP owing to the monograph issued by USP and the heightened standards in the monograph adopted by the FDA. GSK has neither briefed nor argued this issue, therefore I am unable to decide this in the context of the instant Motion. I will permit GSK to

4. Roxane's Decision Not to Acquire USP-Compliant FP

Finally, GSK argues that Roxane's decision not to purchase USP-compliant FP was an intervening cause of Roxane's delayed entry into the market between May 2005, when Roxane was given the opportunity to purchase USP-compliant FP, and November 2005, when Roxane had produced enough USP-compliant units of its nasal spray for a commercial launch. See generally Nat'l Investor Servs. Corp. v. Integrated Fund Servs., Inc., 145 F. App'x 696, 697 (2d Cir. 2005) (affirming a factual finding at a bench trial that defendant's "business decision was an intervening cause, cutting the chain of causation between [plaintiff's] error and [defendant's] ultimate loss."). Plaintiffs respond by drawing a causal chain from GSK's citizen petitions to Roxane's decision not to purchase USP-compliant FP when it was originally offered in May 2005. Specifically, Plaintiffs argue that Roxane's decision to decline to purchase USP-compliant FP in May 2005 was caused by the uncertainty accompanying GSK's as-of-yet unresolved citizen petitions.

Plaintiffs' evidence, when taken in the light most favorable to them, supports their causal chain. Plaintiffs provide testimony from senior employees at Roxane who state that Roxane declined to purchase USP-compliant API in May 2005 because it was aware that as long as GSK's citizen petitions remained pending, its ANDA would not be approved and it would not be allowed to enter the market. Wilson Decl. ¶¶ 14-21 (discussing Roxane's decision not to purchase USP-compliant FP because of GSK's pending citizen petitions).

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raise this issue later in the litigation.

At trial, Plaintiffs will need to prove to the jury that Roxane's decision not to purchase the USP-compliant FP was proximately caused by GSK's citizen petitions and was not motivated by some other unrelated reason. A jury may well conclude that Roxane's decision was an independent business decision that severs the chain of causation that Plaintiffs have attempted to draw. Again, however, whether conduct is a proximate cause or an intervening cause of an injury is a question of fact for the jury. Plaintiffs' evidence is sufficient to raise a genuine issue of fact as to whether Roxane's decision to wait to purchase USP-compliant FP was proximately caused by the uncertainty created by GSK's citizen petitions. Because a reasonable jury could conclude, based upon Plaintiffs' evidence, that Roxane's decision was caused by GSK's petitions, Plaintiffs evidence is sufficient to allow this issue to remain a question of fact.

V. CONCLUSION

Plaintiffs have provided sufficient evidence to raise genuine issues of fact as to whether any of the events that GSK cites as intervening causes of Roxane's delayed entry severs the chain of causation between GSK's conduct and Plaintiffs' injuries. In so doing, Plaintiffs have provided sufficient evidence to raise a genuine issue of fact as to whether GSK's conduct "caused" Plaintiffs' injuries within the meaning of the Clayton Act. As discussed in Part III.A, because Plaintiffs' evidence is sufficient to survive summary judgment on their federal law claims, it is also sufficient to survive summary judgment on Indirect Purchasers' state law claims. I will thus **DENY** GSK's Motion in its entirety.

s/Anita B. Brody

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ANITA B. BRODY, J.

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